

FINAL REPORT

VIRUCIDAL SUSPENSION EFFICACY TEST Enterovirus

TEST AGENT
Nanocomposite Material

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RESULTS

Results are presented in Tables 1-3.

The Viral load was determined in the following manner:

Viral Load ($\text{Log}_{10} \text{TCID}_{50}$) = Titer ($\text{Log}_{10} \text{TCID}_{50}/\text{mL}$) + $\text{Log}_{10}[\text{Volume (mL)} \times \text{Volume Correction Factor}]$

The log_{10} Reduction Factor (LRF) was calculated in the following manner:

Log_{10} Reduction Factor = Initial viral load (Log_{10}) – Output viral load (Log_{10})

The percentage of virus inactivation was calculated in the following manner:

$[\text{1-Output Viral Load} / \text{Initial Viral Load}] \times 100 = 1-10^{(-\text{log}_{10}\text{Reduction Factor})} \times 100$

Table 1
Titer Results

Sample	Titer ($\text{Log}_{10}\text{TCID}_{50}/\text{mL}$)	Volume (mL)	Volume Correction ^a	Viral Load ($\text{Log}_{10}\text{TCID}_{50}$)
Cell viability/media sterility control	no virus detected, cells viable; media sterile			
Virus Stock Titer Control	5.75	-		-
Theoretical viral load per run**	-	-		5.23
Virus Recovery Control (with UV-A) ^b	5.00	3	2	5.78
Virus Recovery Control (without UV-A) ^b	4.75	3	2	5.53
Column Titer Control (with UV-A)	5.25	3	2	6.03
Column Titer Control (without UV-A)	5.00	3	2	5.78
Nanocomposite Material (with UV-A) ^b	≤ 0.83 *	3	2	≤ 1.61

* No virus was detected. The titer was determined based on the Poisson distribution.

** The theoretical viral load was calculated based on the titer of the stock virus and the volume (0.3 mL) added into each reaction mixture.

^a Volume correction accounts for the neutralization of the sample post contact time.

^b Sample was processed by Sephacryl column.

RESULTS (continued)

Table 2
Neutralizer Effectiveness/Viral Interference and Cytotoxicity Controls

Dilution of the Neutralized Sample	Neutralizer Effectiveness/Viral Interference Control (with UV-A) ^a	Cytotoxicity with Control (with UV-A) ^a
10 ⁻¹	virus detected in 4 out of 4 wells	no cytotoxicity observed
10 ⁻²	virus detected in 4 out of 4 wells	no cytotoxicity observed
10 ⁻³	virus detected in 4 out of 4 wells	no cytotoxicity observed

^a Sample was processed by Sephacryl column.

Table 3
Reduction Factor

Test Agent	Contact Time	Initial Viral Load (Log ₁₀ TCID ₅₀)	Output Viral Load (Log ₁₀ TCID ₅₀)	Log ₁₀ Reduction	Percent Reduction (%)
Nanocomposite Material	20 minutes	5.78	≤ 1.61	≥ 4.17	≥ 99.99

CONCLUSIONS

MicroBioTest personnel performed the inactivation procedure using Enterovirus to spike the test agent solution. Samples were taken and titrated by 50% tissue culture infectious dose (TCID₅₀) endpoint assay using LLC-MK2 cells.

Table 3 reports the individual Log₁₀ virus reduction factor for the test article treatment procedure. All of the controls met the criteria for a valid test. These conclusions were based on observed data.